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# THE UNITED STATES OF AMERICA

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September 10, 2003

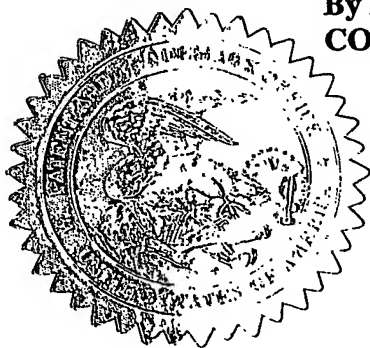
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APPLICATION NUMBER: 60/401,397

FILING DATE: August 06, 2002

RELATED PCT APPLICATION NUMBER: PCT/US03/24484

By Authority of the  
COMMISSIONER OF PATENTS AND TRADEMARKS



*M. Tarver*

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08/06/02

35 U.S.C. PTO

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**PROVISIONAL APPLICATION FOR PATENT COVER SHEET**  
This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)				
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)		
Nigel	Kelly	60 Fulton Avenue, Rye, New York 10580		
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto				
TITLE OF THE INVENTION (280 characters max)				
DROPPER BOTTLE AND ACCESSORIES THEREFOR				
Direct all correspondence to: <b>CORRESPONDENCE ADDRESS</b> <input checked="" type="checkbox"/> Customer Number <span style="border: 1px solid black; padding: 2px;">23869</span>  <div style="float: right; text-align: center;">   <span style="border: 1px solid black; padding: 2px;">23869</span>  <small>PATENT TRADEMARK OFFICE</small> </div>				
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ENCLOSED APPLICATION PARTS (check all that apply)				
<input checked="" type="checkbox"/> Specification	Number of Pages	<span style="border: 1px solid black; padding: 2px;">5</span>	<input type="checkbox"/> CD(s), Number	<span style="border: 1px solid black; padding: 2px;"></span>
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	<span style="border: 1px solid black; padding: 2px;">15</span>	<input type="checkbox"/> Other (specify)	<span style="border: 1px solid black; padding: 2px;"></span>
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76				
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)				
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.		FILING FEE AMOUNT (\$) <div style="border: 1px solid black; width: 100px; height: 40px; text-align: center; margin-top: 10px;">\$80.00</div>		
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees				
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.				
<input checked="" type="checkbox"/> No.				
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are _____				

Respectfully submitted,

SIGNATURE

TYPED or PRINTED NAME Ludomir A. Budzyn

TELEPHONE

973-331-1700

Date

08/06/02

REGISTRATION NO.

40,540

(if appropriate)

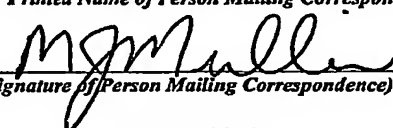
Docket Number:

1181-23P

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This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C.

P19SMALL/REV05

<b>CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)</b> Applicant(s): Nigel Kelly			Docket No. 1181-23P	
Serial No. Unassigned	Filing Date Herewith	Examiner Unassigned	Group Art Unit Unassigned	
Invention: DROPPER BOTTLE AND ACCESSORIES THEREFOR				
<p>I hereby certify that this <u>Provisional Patent Application</u> (Identify type of correspondence)</p> <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D.C.</p> <p>20231-0001 on <u>August 6, 2002</u> (Date)</p> <p style="text-align: right;"><u>M.J. Mullin</u> (Typed or Printed Name of Person Mailing Correspondence)</p> <p style="text-align: right;"><u></u> (Signature of Person Mailing Correspondence)</p> <p style="text-align: right;"><u>EU553056606US</u> ( "Express Mail" Mailing Label Number)</p>				
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1181-23P

**DROPPER BOTTLE AND ACCESSORIES THEREFOR**

Conventional dropper bottles for administering ophthalmic fluid are well known in the prior art. The basic commercial design of such dropper bottles has remained fairly unchanged over the last several decades: a squeezable container is provided with a tapered dispenser that terminates in a discharge aperture. To administer ophthalmic fluid, the discharge aperture is aligned above a target eye and the bottle is squeezed to urge out a drop dose of the fluid (several drops may be required).

Although the conventional design is widely used, it suffers from several drawbacks. Primarily, dose volume is difficult to repeatedly control, in part, because a proper amount of squeeze force is difficult to repeatedly apply to the dropper bottle. Also, accurate control of dose (drop) placement is difficult to obtain.

**DESCRIPTION OF THE INVENTION**

To overcome shortcomings of the prior art, the subject invention is provided which includes various dropper bottle designs and accessories for dropper bottles. This invention relates to improvements in the administration of eye drops, by adding accessories or modifications to conventional dropper bottles, so that a single drop is released in a repeatable and reliable manner. Further features are included which both aid in the alignment of the dropper bottle's nozzle to the eye, and also protect the user's eye from potential damage which can occur

if a pointed nozzle is brought into contact with the eye during alignment. As will be appreciated by those skilled in the art, the various aspects and embodiments disclosed herein may be used singularly or in various combinations.

A first aspect of the subject invention is directed to the problem that most current dropper bottles require the bottle to be squeezed in order to generate pressure inside the bottle and, thereby, expel a drop. This practice is problematic because the user is often unable to determine how hard to press the bottle, and for how long a period of time, so that a single drop is expelled. Usually, more than one drop is expelled, which is wasteful and causes mess. With reference to Figures 1-5, a cradle 10 is depicted which is formed to mount onto a dropper bottle 12 by snapping onto the bottle 12 at the neck 14 and base 16. Mounting of the cradle 10 onto the neck 14 is facilitated by the provision of a hole 18 large enough to allow the bottle 12 to partially pass therethrough (the neck 14 of the bottle 12 may pass through the hole 18; preferably, the hole 18 is sized to not allow the passage therethrough of the reservoir 20 of the bottle 12). Once the cradle 10 is mounted, the bottle neck 14 is pushed off-center from the hole 18 by means of a fulcrum 22 which defines the end of cradle lever 24. The lower end 26 of the cradle 10 registers with an indentation 28 in the base 16 of the bottle 12. As such, the cradle 10 traps the bottle 12 at three points: at the hole 18; at the fulcrum 22; and at the lower end 26 of the cradle 10.

In use, free end 30 of the cradle lever 24 is pressed towards the bottle 12 as the bottle 12 is inverted to deliver a drop. As the free end 30 is pressed inwardly, the fulcrum 22 indents a side of the reservoir 20 adjacent to the neck 14, thus expelling a drop. At the point where a drop is expelled a toe 32 of the cradle lever 24 clicks into a recess 34 defined in the lower end 26, with

an audible or tactile 'click' indicating that a drop has been released from the bottle 12. Upon detecting this 'click' the user releases the free end 30 of the lever 24, which springs back to its fully open position (shown in Figure 1). Further drops may then be released.

In a second aspect of the subject invention, a nozzle 100 is provided on the dropper bottle 12 which is surrounded by a protruding outer collar 102 (Figure 4). Preferably, the collar 102 is annular. The collar 102 projects beyond tip 104 of the nozzle 100 such that, if contact is made with an eye during use, the outer collar 102 will contact the eye and not the nozzle tip 104. The greater (flat) surface area 106 at the front of the collar 102 will be less likely to cause the user any eye damage than the sharper nozzle tip 104. The nozzle 100 may be constructed from plastics such as Polyethylene or Polypropylene, or softer elastomers may be used as a further safety measure.

In a third aspect of the subject invention, a nozzle of a dropper bottle may be colored to further aid in the alignment process, with colors being more easily visible to the eye than the colorless plastics used in conventional dropper bottle nozzles. As a further aid to alignment, as shown in Figure 5, nozzle 200 may be directed at an angle to aid the placement of drops into the eye.

In a fourth aspect of the subject invention, with reference to Figures 6-8, a device 300 is provided which limits the degree of deformation of the bottle 12 to such an amount necessary to expel one drop. The device 300 includes a series of outwardly-extending branches 302, like tree branches, which project from a central tube 304 which is in communication with nozzle 306.

Preferably, the central tube 304 is fixed to the nozzle 306. Any method may be used to fix the device 300 to the bottle 12 including an interference fit in the neck 14 of the bottle 12. A locking detent 308 may be also provided to enhance the fixation of the device 300 to the bottle 12. For installation, the device 300 is inserted through the neck 14 with the branches 302 bending over during installation (Figure 6) and springing back to their original shape (Figure 7) after installation. As shown in Figure 8, once installed, the branches 302 limit the amount by which the wall of the reservoir 20 may deflect inwardly before contacting ends of the branches 302.

In a fifth aspect of the subject invention, a device 400 is provided which limits the amount of liquid dispensed by a dropper bottle 12 to one drop. The device 400 generally includes a ball 402 which is free to run within a tube 404. The tube 404 extends from nozzle 406 and has a number of slots or openings 408 formed therethrough which allow fluid communication between the inside of the tube and the inside of the reservoir 20. The end of the tube 404 adjacent to the nozzle 406 has a parallel section 410 sized to snugly fit the ball 402. The parallel section 410 communicates with nozzle bore 412 to exit the bottle 12. In use, the ball 402 drops to the bottom of the bottle 12 when the bottle is rested on its base 16 (Figure 9). As the bottle 12 is inverted for use (with the nozzle 406 being directed downwards) (Figures 10-11), liquid in the reservoir 20 enters the openings 408 to flood the inside of the tube 404, and the ball 402 drops down through the tube 404 towards the nozzle 406. As the ball 402 reaches the parallel section 410, the parallel section 410 would have been already flooded and fully charged with liquid (Figure 10). The ball 402 generally seals the parallel section 402 from remaining portions of the tube 404. Applying pressure to the wall of the reservoir 20 (such as with normal drop administration), the ball 402 is forced through a defined stroke of the parallel section 410

which in turn displaces fluid along its path resulting in an expelled drop of equal volume to the swept volume of the ball 402 (swept volume being the displaced volume during travel of the ball 402). As the ball 402 reaches the end of travel it will shut-off against a seat 414 and no more liquid can be expelled (Figure 11).

In a sixth aspect of the subject invention, an alternative to the above means of expelling a drop is provided by a sprung-loaded piston 500 as shown in Figures 12-13. In this configuration, the piston 500 (and associated bore 502) is preferably parallel to the nozzle bore 504, and operates inwards towards the base 16 of the bottle 12 so that, upon pressing the piston 500, a pressure rise is created in the bottle 12. This rise in pressure will expel a drop from the bottle 12 when the bottle 12 is inverted for use.

In a seventh aspect of the subject invention, as shown in Figures 14-15, a design 600 is provided which includes a nozzle 602 that is normally sprung-loaded outwards towards a user (Figure 14). A cradle 604, which snaps into location with the nozzle 602 and the bottle base 16, is used to impart inward (downward motion towards the base 16) motion to the nozzle 602 by pressing a free end 606 of the cradle 602 inwards towards the bottle 12. A forked end 608 of the free end 606 translates across a rounded face 610 of the nozzle 602 and the angled approach of the forked end 606 drives the nozzle 602 against a spring 612 (in the direction of the base 16). The nozzle 602 has a piston seal 614 which cooperates with the neck 14 of the bottle 12 to make a seal, and it is the translation of this piston seal 614 which generates a pressure rise in the bottle 12 and administration of a drop.



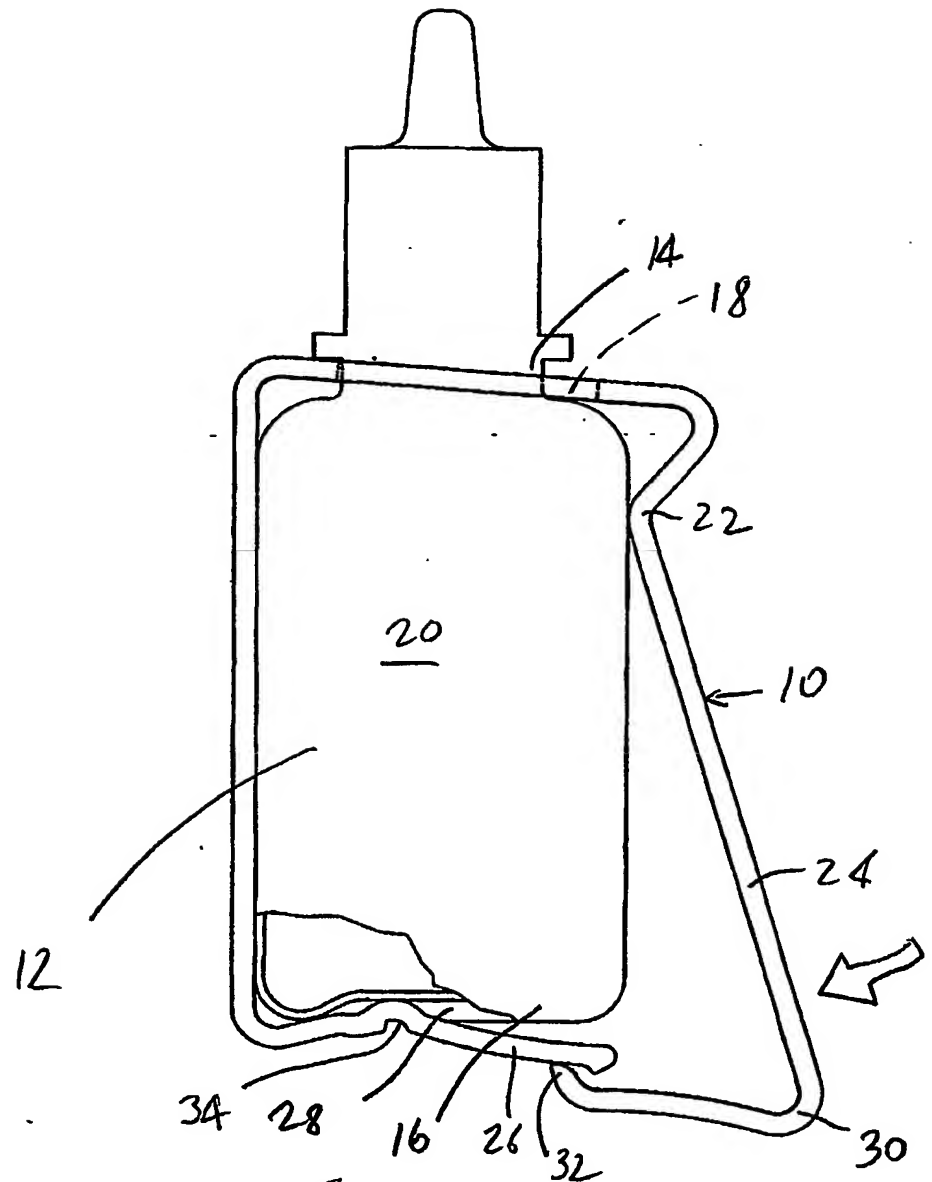
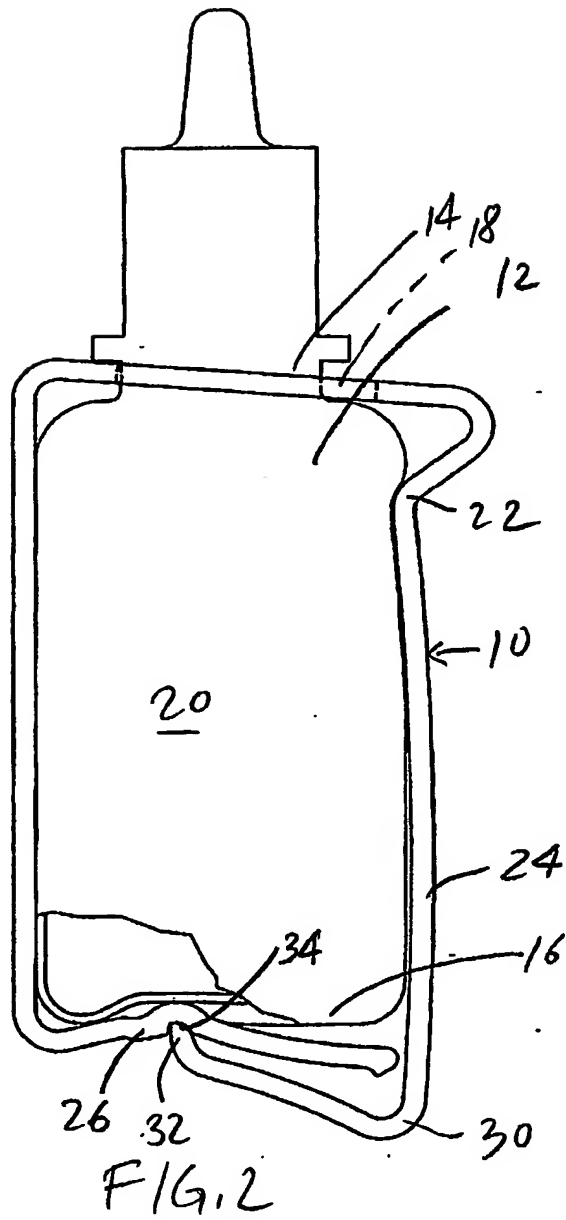


FIG. 1



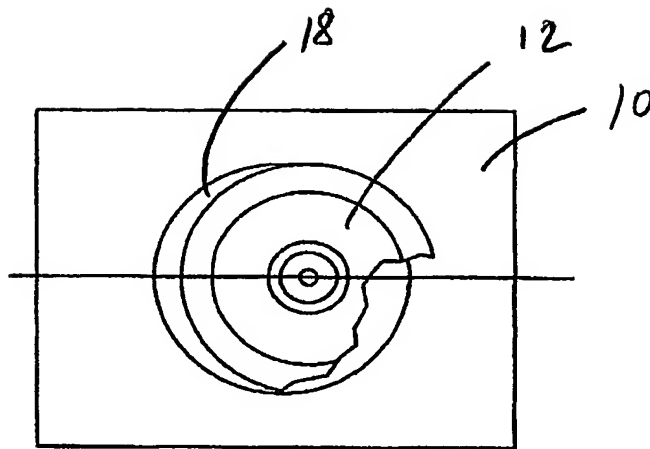


FIG. 3

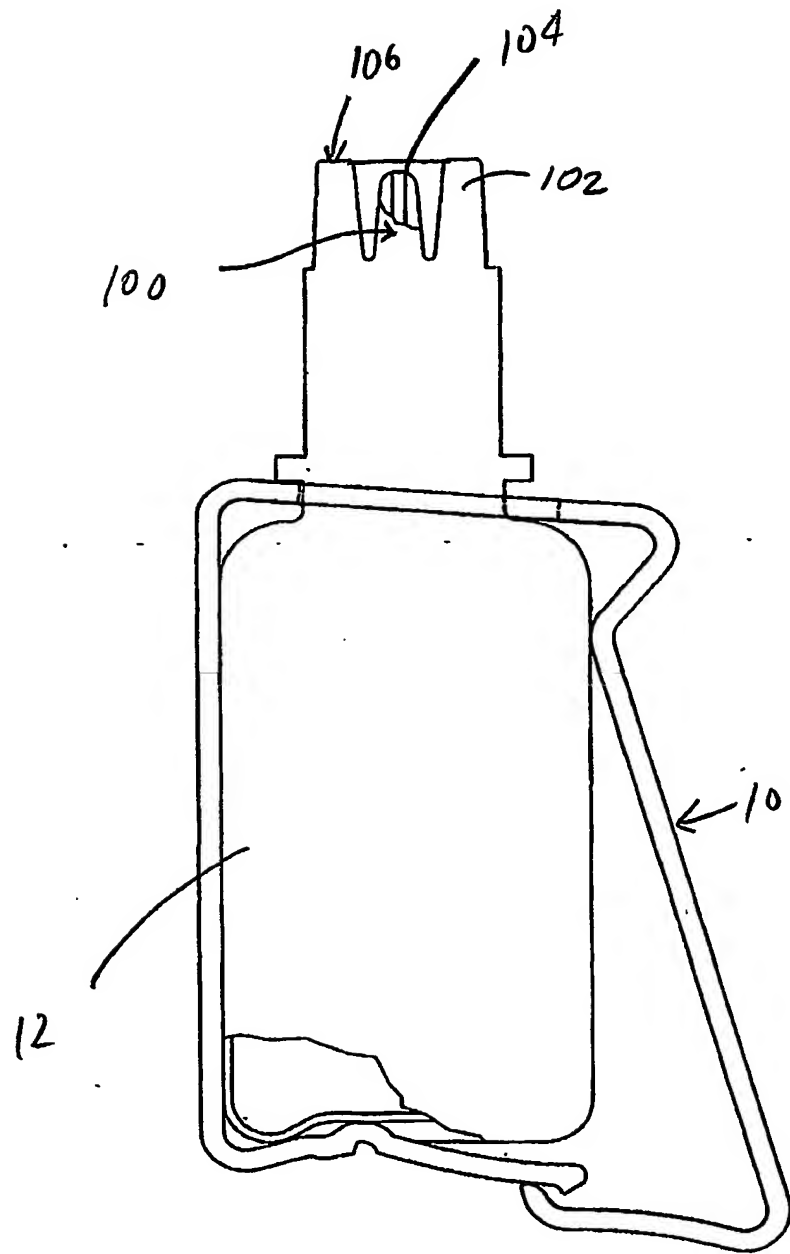


FIG. 4

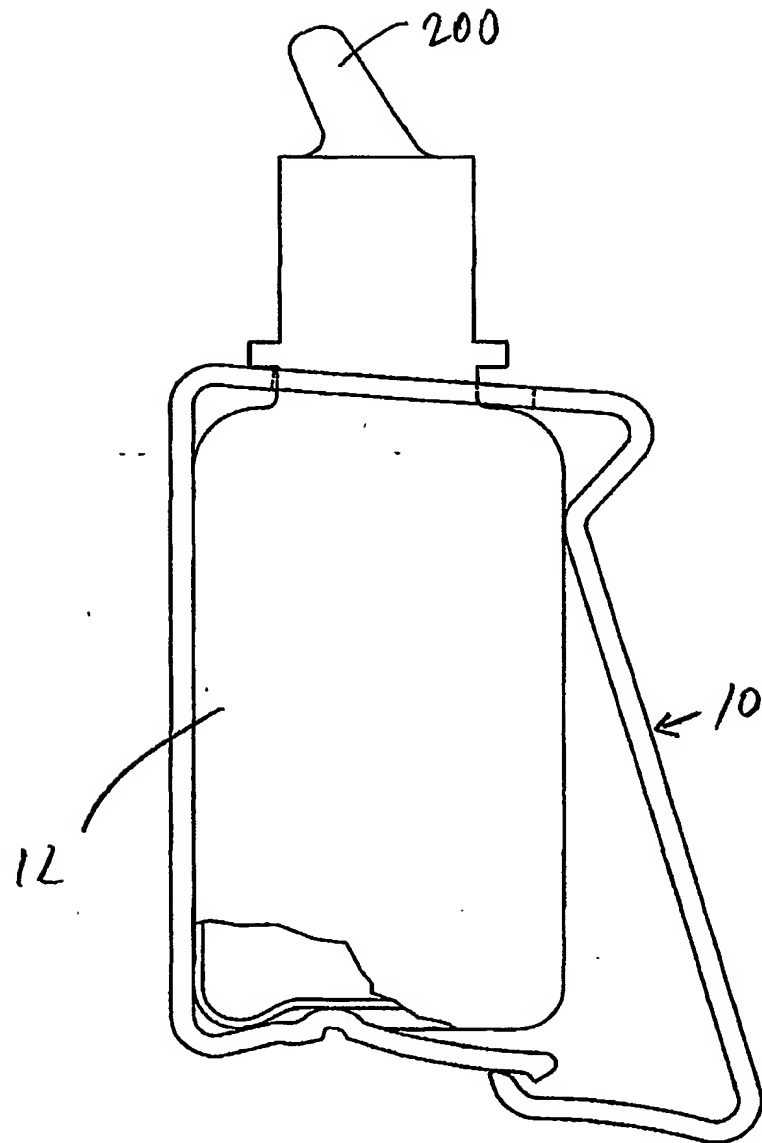


FIG. 5

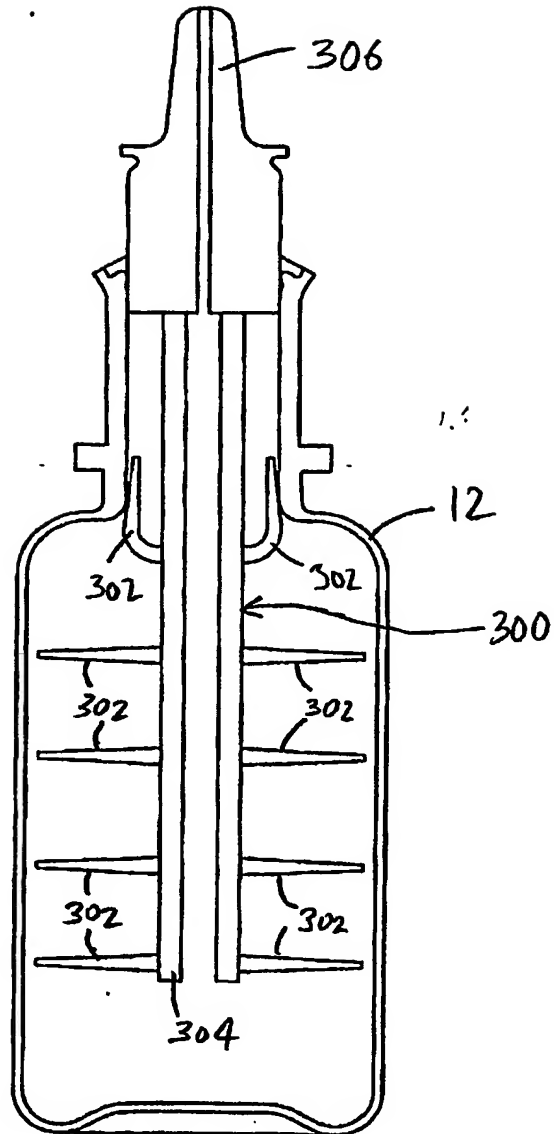


FIG. 6

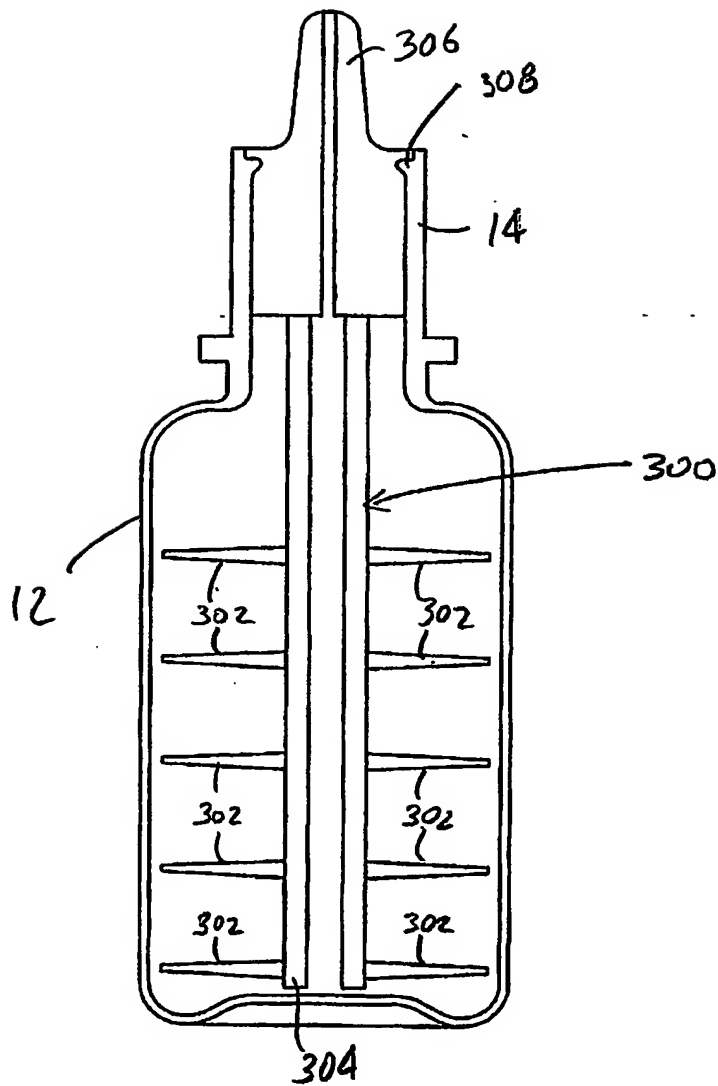


FIG. 7

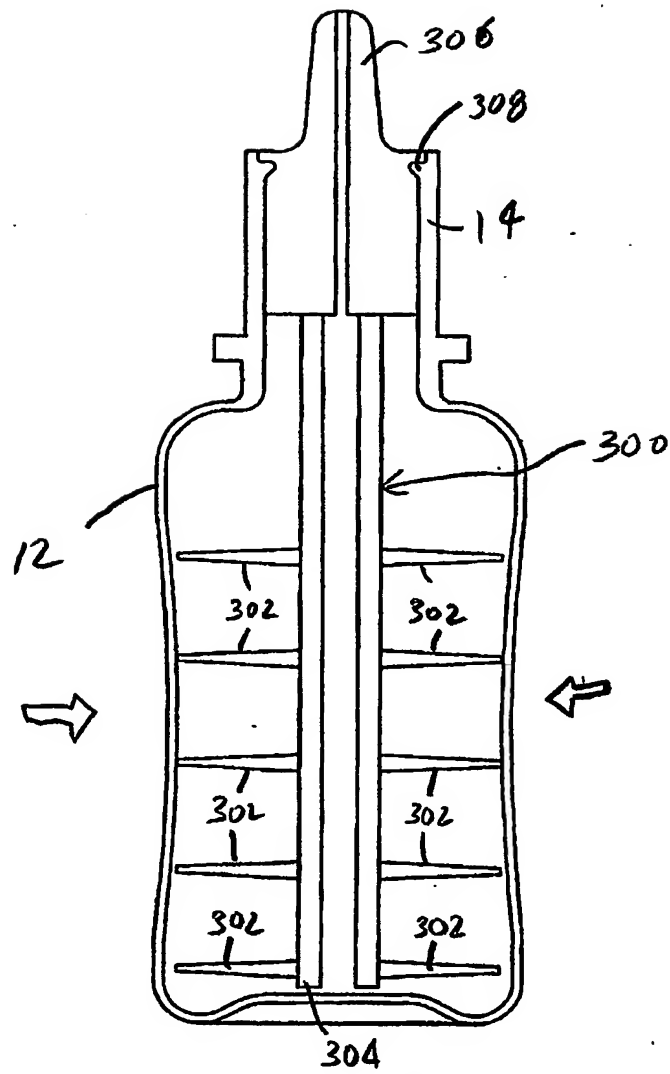


FIG. 8



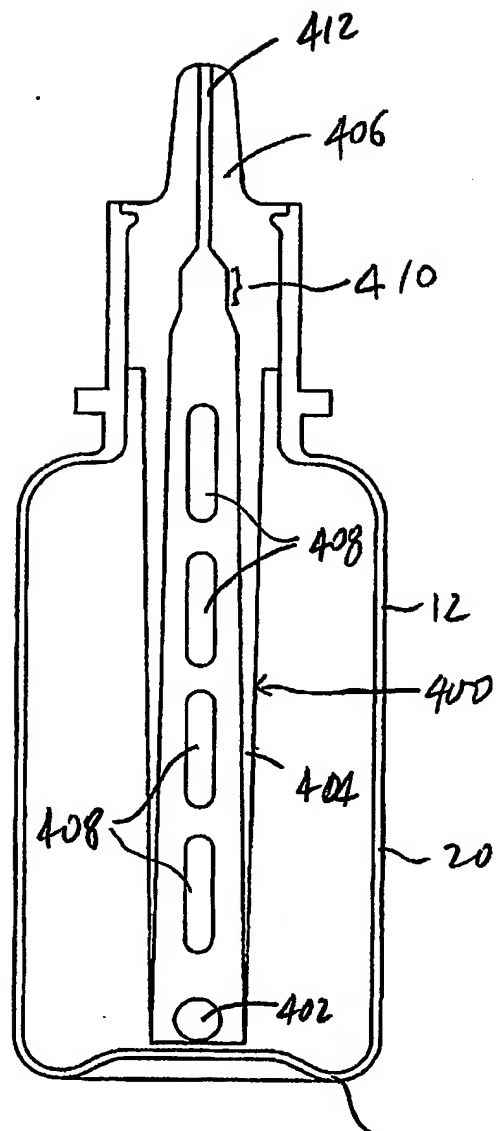


FIG. 9 16

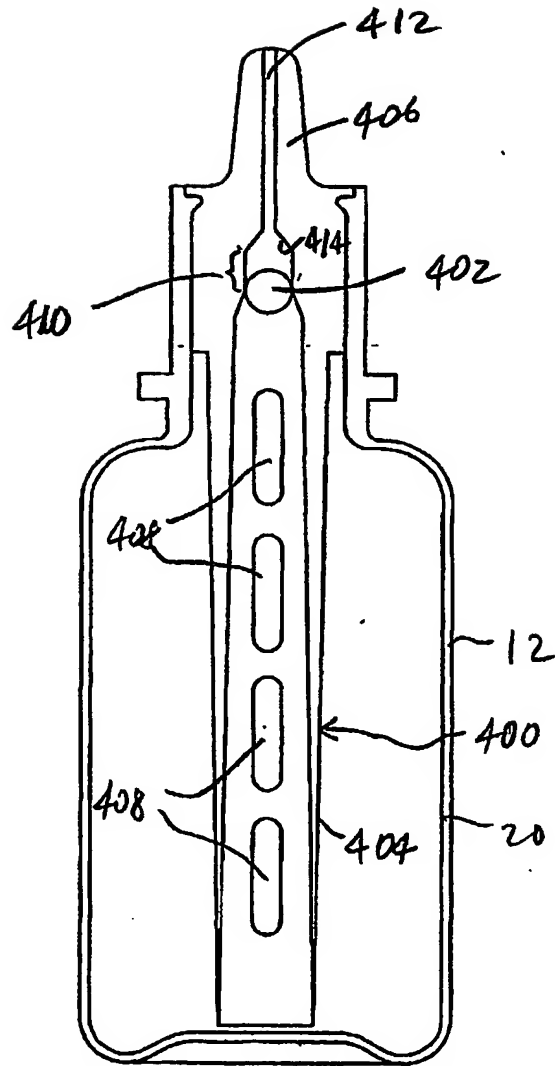


FIG. 10

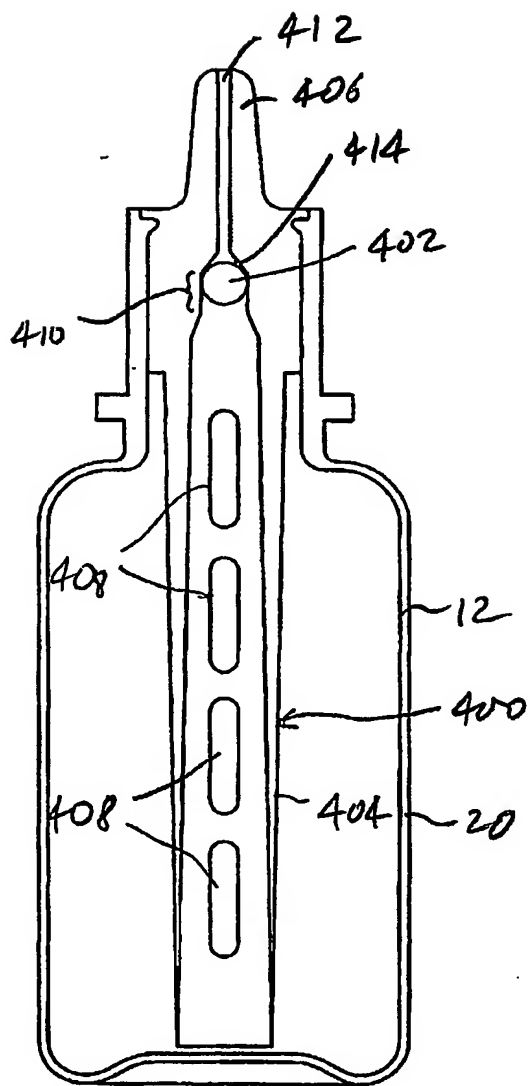
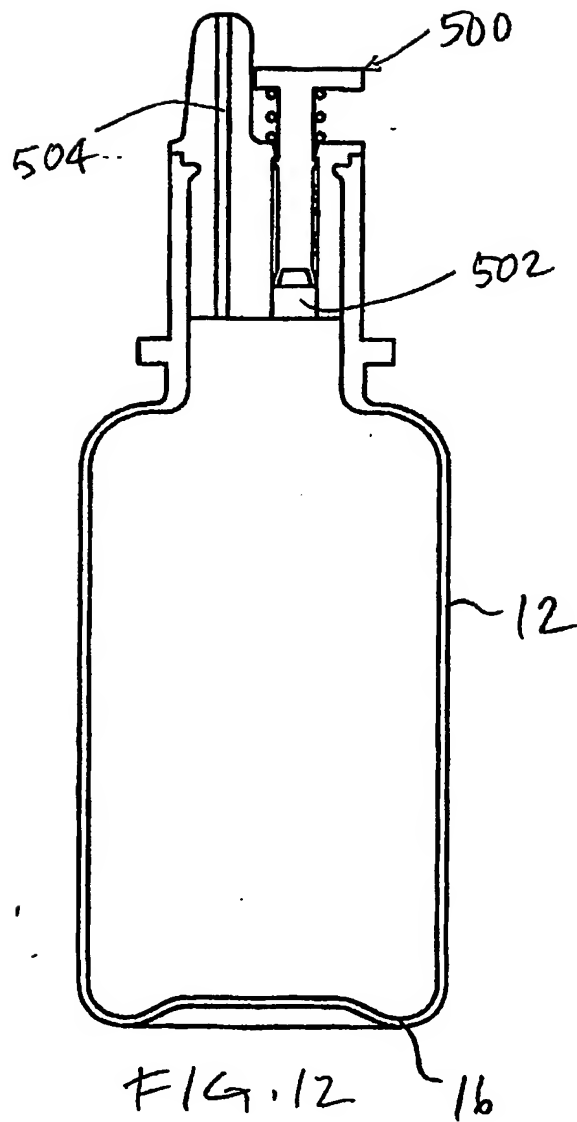
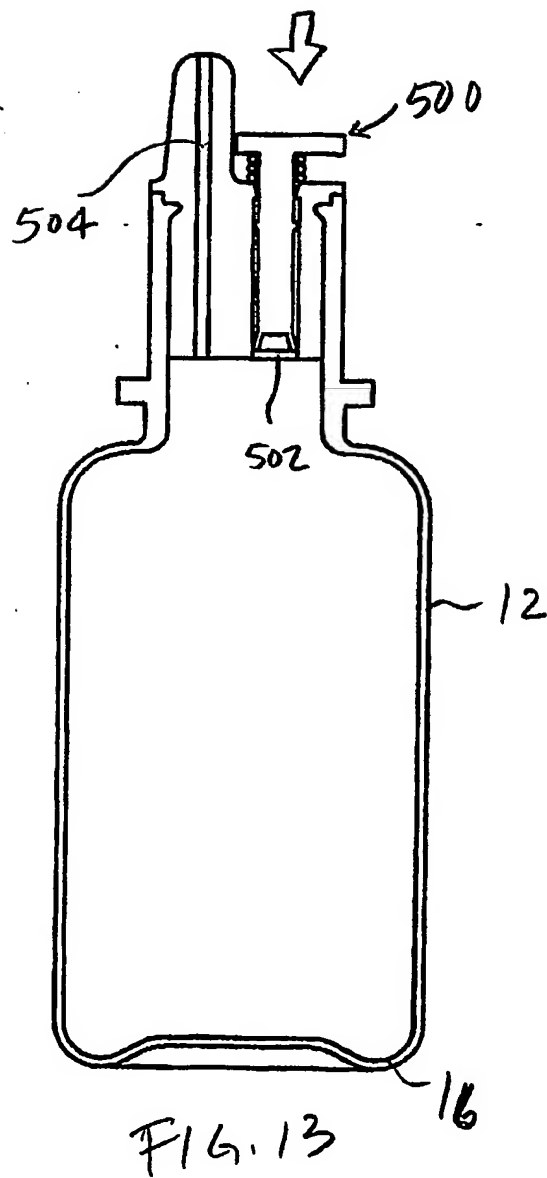


FIG. 11





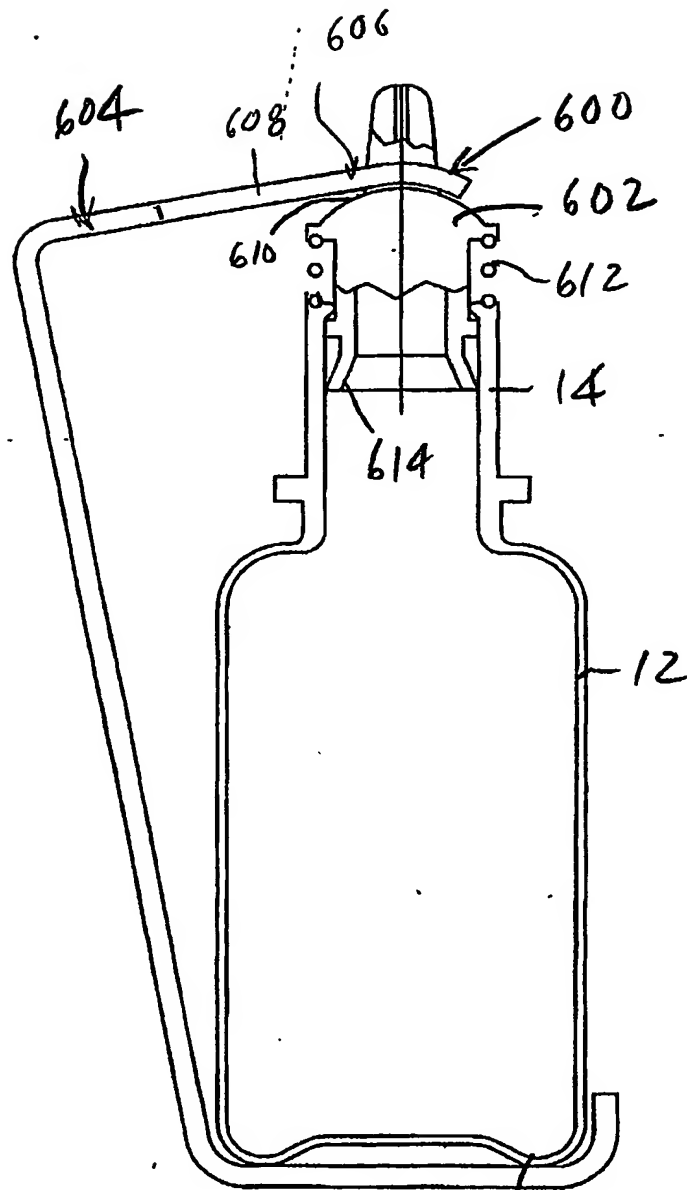


FIG. 14

